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## **PSYCHOSOCIAL INTERVENTIONS IN OST SERVICES:**

### **Does the evidence provide a case for optimism or nihilism?**

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#### **Conflict of Interests Statement**

ED has received honoraria to deliver training or lectures in the management of opiate dependence by PCM Scientific, a medical education company, as part of the Quality Patient Care Network and the Improving Outcomes in the Treatment of Opiate Dependence conference.

ED has received an honorarium from the National Treatment Agency for the Treatment of Substance Misuse for developing treatment manuals for use in drug treatment services.

ED is currently a co-investigator on 2 grants from the NIHR Health Technology Assessment fund, and has recently been lead investigator on a grant from the NIHR Research for Patient Benefit fund. All three grants involved the treatment of opiate dependent populations with a psychosocial intervention with or without medication

ED is employed by the Institute of Psychiatry, Psychology & Neuroscience, King's College London. The Addictions department has been/is currently in receipt of research grants from the National Institute of Health Research (NIHR), the Medical Research Council, and other charitable and commercial organisations (including Martindale, RB Pharmaceuticals, iGen).

ED and LM are partly or solely employed by the National Health Service, a provider of opiate substitution treatment services and associated psychosocial interventions.

LM is a lead researcher on a RCT exploring the effectiveness of a psychosocial programme in enabling clients on opiate substitute medication to abstain from crack and heroin funded from an untied educational grant from Reckitt Benckiser

LM is a clinical advisor to the Public Health England Alcohol, Drugs and Tobacco Division, Health and Wellbeing Directorate (secondment 1 day a week).

## **Abstract**

Clinical guidelines from around the world recommend the delivery of psychosocial interventions as part of routine care in opiate substitution treatment (OST) programmes. However, although there are numerous individual studies demonstrating benefit for structured psychosocial interventions, meta-analytic reviews find no benefit for manual-based treatments beyond 'routine counselling'. The authors consider the question of whether OST medication alone is sufficient to produce the required outcomes, or whether greater efforts should be made to provide high quality psychosocial treatment alongside medication. In doing so they consider the nuances and limitations of the evidence, and conclude by suggesting ways in which the research community may try to explore these issues in the future. Steering a path between overly optimistic or nihilistic interpretations of the value of psychosocial treatment appears to be the most pragmatic approach.

## What is Being Debated?

Fifty years since it was first introduced, the evidence base for the efficacy of opiate substitution treatment (OST) in reducing illicit opiate-related harms is extensive (1). When OST was first presented as a treatment strategy for opiate dependence in the 1960s, the process of prescribing methadone went hand-in-hand with efforts at psychosocial rehabilitation.

*“We have in common the goal of enabling previously criminal persons to lead socially acceptable, crime-free lives. This will not be done simply by dispensing methadone. If crime is to be reduced significantly, we need an effective rehabilitation program” (2)*

A review of OST clinical guidelines from around the world suggests that psychosocial interventions are still a crucial part of treatment (3-6). Every guideline mentions of the need for psychosocial treatment or counselling, and some devote up to 10% of the document to detailing these interventions. However, RCTs have provided evidence for the effectiveness of directly administered methadone without drug abuse counselling for one month (7), four months (8), or six months (9), and systematic reviews suggest that methadone without counselling is more effective in reducing substance use than being waitlisted for treatment or receiving psychosocial treatment with or without placebo (10). Studies of office-based OST delivered with minimal or no counselling beyond standard medication management show rates of treatment retention and improvement in illicit drug use comparable to OST with counselling (11-13). Some commentators have suggested that in contrast to ‘*an implicit judgement that medication is only an adjunct to the “truly effective components” of counselling and recovery work*’, there is an argument that medication itself is treatment, and that psychosocial interventions may not be needed at all (at least for some) (14).

The authors have recently been members of the psychosocial interventions sub-group of the expert committee reviewing national guidelines for the treatment of drug misuse in the United Kingdom. The UK is committed to evidence-based treatment, and so we consider the debate around the strength of the

evidence base to support psychosocial interventions alongside OST, and suggest possible ways of moving things forward.

### **Evidence for psychosocial interventions for drug misuse**

Psychosocial interventions form the mainstay of treatment for (non-opioid) drug dependence. Carroll has noted the impressive evidence base emerging for them through increasingly sophisticated clinical trial methodology (15), citing systematic review-based evidence for contingency management (16), family therapies (17), motivational interviewing (18) and relapse prevention (19). A systematic review and meta-analysis of psychosocial interventions for all substance use disorders identified 35 treatment trials involving 2,340 patients (20). Treatments evaluated included contingency management, relapse prevention, general cognitive behaviour therapy, and treatments combining cognitive behaviour therapy and contingency management. Overall, such treatments provided benefits reflecting a moderate effect size ( $d=0.45$ ).

### **Its all down to the medication: The case for therapeutic nihilism**

However, the picture is less clear when the efficacy of additional psychosocial services in OST is considered. Amato and colleagues reviewed 13 different treatments in a meta-analysis of 35 studies including 4319 participants (21). There was no benefit for any psychosocial intervention plus any maintenance pharmacological treatment when compared to standard maintenance treatment in terms of retention in treatment, opiate abstinence during or after the treatment, compliance, or psychiatric symptoms. The authors concluded that adding any psychosocial support to standard maintenance treatment did not add additional benefits. A review of a further 22 studies (22) supported the efficacy of providing psychosocial interventions in combination with medications to treat opioid addictions, but found that the incremental utility varied across studies, outcomes, medications and interventions. More importantly from a UK perspective, a systematic review of the same literature by the National Collaborating Centre for Mental

Health only found evidence for contingency management and mutual self-help (23), concluding that cognitive behavioural therapy and psychodynamic therapy focused on the treatment of drug misuse should not be offered routinely to people receiving opioid maintenance treatment. This evidence appears to contradict the importance attributed to psychosocial interventions in OST clinical guidelines, and undermines recent expert group guidance in the UK (24). So why is there a gap between routine practice and research evidence?

### **The complexity of the opiate-using population seeking treatment**

The evidence for treatment of heroin dependence suggests poorer outcomes than for equivalent groups with other drug or alcohol problems (25). When the impact of psychosocial treatments is compared, interventions for cannabis use produce the greatest effect sizes ( $d=0.81$ ), followed by cocaine use ( $d=0.62$ ), opiate use ( $d=0.39$ ) and polysubstance use ( $d=0.24$ ) (20). People with heroin dependence have a greater likelihood of life problems prior to dependence, including being the victim of sexual and/or physical abuse during childhood, or growing up in families with parental drug and alcohol abuse (26). Once established, the predominant trajectory is long-term dependence, with abstinence rates of 30% or lower after 10 years of observation and remaining stable thereafter with no 'maturing out' effect (27, 28).

Consideration of an opiate-using 'career' is helpful (29, 30), but there is not one single trajectory and early quitters do exist (27, 31). Potential turning points occur where the trajectory is deflected towards abstinence, and entry into treatment is one of the most significant (26). However, cohort studies of opiate dependent individuals report 6-10 years of opioid use prior to treatment entry (27), and by then users have typically developed dependence and a range of serious, life-threatening drug-related problems. The illicit nature of heroin use means that it is strongly associated with crime and imprisonment, and the social stigma of use leads to low self-esteem, difficulty in finding work and loss of contact and support from family and friends. Users of both illicit and prescribed opiates perform poorly in tests of attention, executive function

and information processing when compared to healthy control subjects (32, 33). Added together, these factors mean that episodes of psychosocial treatment may be unsuccessful and relapse rates are high. It is extremely unlikely that a single treatment episode will result in abstinence recovery.

### **Specific issues with psychosocial intervention research in OST populations**

A major problem with the evidence base is that the control intervention used in OST studies routinely includes counselling sessions in addition to methadone, leading Amato and colleagues to conclude that their review *'did not evaluate the question of whether any ancillary psychosocial intervention is needed when methadone maintenance is provided, but the narrower question of whether a specific more structured intervention provides any additional benefit to a standard psychosocial support'* (21). In contrast, large outcome studies of OST services have concluded that agencies with more and better psychosocial interventions have better outcomes (34-36). A study of six methadone programmes in the USA found those providing more treatment services were associated with less heroin and cocaine use, less injecting, and less criminal behaviour among their patients (34). The most successful services provided regular counselling of good quality, achieved a high rate of attendance through a long-term maintenance and rehabilitation policy, and viewed counselling as the most important part of the rehabilitative process. Other large cohort studies have produced similar findings (35, 36).

Therefore, the concept of 'psychosocial intervention' includes more than just a psychologically-driven treatment. A key RCT also pointed to a dose-response relationship for 'dose' of psychosocial support over the 6-month experimental period: the more treatment received the better the outcome (37). Opioid users entering treatment were maintained on a steady dose of 60-90mg methadone and randomised to one of three counselling conditions. The low-intensity group received methadone only (with minimal counsellor contact), the medium-intensity group methadone plus standard counselling (one session per week, adjusted according to weekly urinalysis results), and the high-intensity group methadone plus standard counselling

enhanced by other clinical services (sessions with a psychiatrist, employment counsellor, family therapist). The study showed that psychosocial interventions can improve the outcome of methadone treatment, but that a subset of patients in all study conditions performed well. At 12 months, the total cost per abstinent participant was lowest for the medium-intensity group. Therefore, it was possible to conclude that high levels of psychosocial support are not cost effective for all opiate dependent patients (38, 39). Some do well with methadone plus psychosocial intervention, as received by the intermediate-level treatment group, some need more intensive care, and others function well with methadone alone and little or no psychosocial support.

There are further problems in defining the most appropriate outcome measure for psychosocial components of OST, with retention in treatment and abstinence from the primary problem drug most commonly reported (21). If opiate dependence is conceptualised as a chronic health problem such as hypertension, it might be expected that the consequences of the disorder will be prevented as long as the patient takes the medication, but will recur when the medication is stopped (14). It is therefore not clear where the ancillary psychosocial intervention fits into this model, and whether reduction in opiate use is a suitable outcome measure for judging its effectiveness. Secondary outcomes are less often reported in a comparable way, and include compliance (i.e. number of psychosocial sessions attended), craving, psychiatric symptoms/psychological distress, quality of life, severity of dependence, and death (21).

Another complicating factor in interpreting the evidence is the dose of intervention received. Treatment of people with complex needs is associated with a high rate of dropout, and up to 50% of new admissions may exit against clinical advice (40). In Dutra's analysis of psychosocial therapies for any illicit substance, one-third dropped out of treatment groups before trial completion. The evidence suggests that rates are even higher in OST populations (41), with mean attendance rates in systematic reviews ranging between 23% and 68%, despite optimal treatment conditions (21).



## **Issues with training and supervision**

In common with healthcare systems around the world, the global economic slowdown has impacted on healthcare provision in England. The Government's policy of austerity has reduced the availability of treatment services for addiction, with 40% cuts in treatment budgets in some areas (42). Non-medical staffing accounts for about 50% of the treatment budget, and the largest group of staff are the 'drug workers', a group made up of clinicians from a range of backgrounds. The role of the drug worker is not always clear, and staff perform a number of administrative, therapeutic and case management roles (34, 43, 44) in addition to taking primary responsibility for the delivery of the psychosocial component of treatment. As budgets are cut and caseloads rise, clinicians face an increasing administrative burden, including the requirement to complete treatment outcome measures, complete care plans, formally assess risk and attend to child safeguarding issues.

It has proved very hard to train clinicians to deliver formal psychosocial interventions in practice. Staff are unclear on their role (43), and have little time, training or supervision in many services. The gap between research knowledge and clinical practice has been described as '*both persistent and formidable*' (45), meaning that '*the majority of treatment programs in the United States remain grounded in traditional counseling models that have largely not been evaluated rigorously*' (45). The quality of clinician training is variable, and rates of clinician turnover are high. Establishing the efficacy of a treatment approach in a clinical trial rarely ensures that it is used in routine practice.

A review of four decades of addiction treatment outcome research led Miller and Moyers to conclude that substantial differences among therapists in client outcomes are common, and relational factors such as therapist empathy and therapeutic alliance can be significant determinants of addiction treatment outcome (46). This is equally true for therapists in OST services, where both therapist characteristics and technique are associated with a better outcome, but better therapist characteristics more so than technique (47). Therapists have often been incorporated in statistical analysis as if they were a fixed form of treatment, and

should be treated as if they were a random selection from the population of therapists that practice that therapy (48).

### **The importance of organisational factors**

In addition to patient characteristics and staff competencies, measures of organisational functioning are also associated with treatment outcomes. The large DATOS study reported one year retention rates between 10 different OST programs ranging between 15% and 76%. Although the services with the lowest retention rates treated clients with the most difficult problems (more alcohol and cocaine dependence, more psychological problems), the broad set of client attributes examined was not sufficient to explain the observed variations in retention rates (49). Organisational culture, including overall mission and the importance afforded to training and staff development, has been shown to be associated with treatment outcomes in the UK and beyond (50, 51). However, such organizational culture is damaged by frequent re-tendering of clinical services, which has been identified as a potential threat to the quality of drug treatment in the UK (25).

### **Four Ways to Move Forward**

There is a broad acceptance that psychosocial interventions are needed within OST, but research evidence doesn't tell us how they should be delivered, to whom, and with what goal in mind. We suggest four possible ways forward?

#### **1. Stop packaging psychosocial interventions into 'branded' products**

Research in populations receiving OST falls foul of many of the criticisms previously levelled at 'packaged' psychosocial interventions (52). Here is another example of the equivalence paradox in psychotherapy

research, whereby active interventions are better than no intervention but no one treatment prevails.

Relationship is neglected in favour of technique, and psychosocial treatment is seen *‘like a medication, as a piece of technology that requires only therapist skill and efficiency and patient compliance in order to be delivered’* (52).

However, despite equivocal findings for ‘brand-name’ treatments, specific behavioural treatment components and practitioner competencies have been linked to more favourable outcomes in both alcohol and smoking cessation research (53, 54). Moos has outlined the common elements of effective treatments, and shown that these are similar in both natural recovery (55) professionally- or peer-led recovery (56). Therefore it may be helpful in both research and clinical practice in OST to create a typology of the techniques that are effective, and build treatment strategies from the bottom upwards.

## **2. Focus on staff skills to deliver psychosocial interventions**

*“The concern about costs and the recent cutbacks in funding for addiction treatment have worsened the paradox that has long existed in the field of addiction treatment. Although the patients suffer from the most complex combinations of medical, psychiatric and social problems, the modal therapist is a counsellor with very little formal training and often a distrust for scientifically based treatments”* (39)

This quote from O’Brien was published nearly 20 years ago, but can anything be said to have changed in that time? The UK has seen work on developing packages of care for use in OST services (57), and on developing core competencies for staff in delivering them (58). The recent focus on the importance of a clinician’s ability to form a therapeutic alliance (46) suggests that this should be the priority in treatment services before introducing technical aspects of treatment. By breaking down the treatment process into smaller units, it should be possible to train staff ‘from the bottom up’, equipping them with simple skills and ensuring that they are supervised adequately to deliver them.

## **3. Research treatment systems, not individual interventions**

An evidence base built on the RCT encourages manualised interventions that don't translate easily to routine clinical practice. Evaluating the treatment system as a whole is an alternative approach, specifying minimum basic standards and then evaluating the addition or removal of individual components. Models to understand the 'black box' of treatment have been articulated (59), and have the advantage of setting up testable hypotheses about the effectiveness of components applied at different stages in the treatment journey. The pharmacological and psychosocial components of care have different objectives (reducing drug-related harm and providing stabilisation versus tackling the underlying causes of addiction and developing the skills to overcome them), and greater sophistication is required to understand their roles and interactions. For example, there is good reason to believe that levels of motivation for change may differ at different stages of a treatment career, and there has been relatively little focus on what works to help a client move from stable maintenance on OST to total abstinence. This is particularly relevant in the UK, where there has been a political focus on people being 'parked' on methadone, implying that insufficient is being done to help people move on with their lives (25).

Considering treatment systems also allows an examination of 'stepped care', whereby the intensity of intervention is titrated to the needs of the individual at a particular point in time. RCTs have shown that enhanced services produce better results, but that some patients have difficulty taking advantage of them. There appears to be a minimum level of psychosocial therapy that is necessary within any OST programme. More intensive therapy improves the clinical outcome, but only when matched to assessed need and even then reaching a ceiling effect (60). Evaluating an entire treatment system would increase scale, but also allow the removal of the artificial conceptual split between medication and psychosocial elements of treatment. For example, Brooner and colleagues have combined the principles of contingency management with OST medication to enhance engagement with psychosocial interventions (61-63). Finally, a systems approach might allow more consideration of what helps ensure that effective interventions are delivered in real world situations. The issue of technology transfer has been under-researched in the addictions field (64).

#### **4. A treatment system includes both professional and peer-led elements**

OST services in the UK have been accused of lacking ambition for their patients, and a greater emphasis has been placed on 'exiting treatment drug free' as a main treatment outcome since 2010 (65). Although this has led to an unhelpful debate about the merits of harm reduction and abstinence, it has also developed the idea of a 'recovery community' and its potential role in helping people stop using opiates (66, 67). There has been a move to shift addiction treatment from an acute care model of biopsychosocial stabilization to a model of sustained recovery management, nesting this within larger recovery-orientated systems of care (68, 69). Evidence-based guidelines have emphasised the benefits of mutual self-help (23), but there is insufficient research to support Narcotics Anonymous attendance in helping people to move from OST to abstinent recovery (70). OST and 12-step programmes have been considered incompatible (71), as some consider the use of any medication to treat addiction as the antithesis of the first step i.e. '*a continued effort at control rather than surrender*' (72). The level of acceptance of OST patients within 12-Step groups in England is unknown, and in particular whether restrictions on them are the same as those described in the USA (e.g. the right to claim "clean time", speak at meetings, sponsor others or hold service positions) (72, 73).

In cost-cutting times, the emergence of recovery coaches and mentors that may fill the gap between professionally-delivered psychosocial interventions and mutual self-help is interesting, but has little supporting evidence yet. New recovery support institutions are rising within the space that has existed between professionally directed addiction treatment services and peer-based mutual-aid societies. These have not yet been fully evaluated in the scientific literature (74, 75), and evaluating whole 'recovery-orientated integrated systems of care' would be one way of doing this.

#### **Conclusion**

The evidence base for psychosocial interventions in OST services can be interpreted both positively and negatively, and the implications are significant for the cost of treatment provision. It may be wrong to think we can amass enough evidence to completely understand a complex issue such as opiate dependence, with its mix of biological, psychological and social underpinnings. However, when faced with equivocal evidence it is important to find a sensible way through that doesn't adopt one of the polar extremes of psychosocial interventions for everyone or no one. Perhaps now is the time to be honest about the limitations of our knowledge, and persuade the funders of treatment services that both medication and psychosocial treatment are useful but the skill lies in blending them both into an effective treatment system rather than choosing one or the other.

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